OAK RIDGE NATIONAL LABORATORY
MANAGED BY LOCKHEED MARTIN ENERGY RESEARCH CORPORATION
FOR THE U.S. DEPARTMENT OF ENERGY

POST OFFICE BOX 2008
OAK RIDGE, TN 37831-6120

PHONE: (423) 576-8594
FAX: (423) 576-7956

INTERNET: jenkinsra@ornl.gov

March 11, 1998

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
MD EC-14
79 Alexander Drive
Research Triangle Park, NC 27709

Dr. Dr. Jameson:

I am responding to the call for public comment regarding the National Toxicology Program's intent to review a variety of substances for possible listing or de-listing from the Report on Carcinogens, Ninth Edition. My comments and enclosures specifically relate to the potential listing of Environmental Tobacco Smoke (ETS) in the Ninth Edition. The call for public comment requests input in a number of areas, including human exposure. You may be aware of the fact that my associates and I, Drs. Guerin and Tomkins, are co-authors of a monograph on ETS composition and measurement, which was published in 1992. That book summarized the state of knowledge at the time with regard to the levels of ETS to which individuals exposed.

Since that time, I have been the principal investigator for a number of studies which have been directed toward determination of personal exposure to ETS. I wanted to be sure that you had copies of the published manuscript from the so-called 16 Cities Study, plus two additional manuscripts which have been or are being submitted for publication in the peer reviewed literature from that study to date. In addition, I wanted to provide you with copies of the slides from two presentations which were given last Fall (1997) at the Tobacco Chemists Research Conference. These presentations describe the initial findings from a study of personal exposure to ETS of waiters, waitresses, and bartenders in the Knoxville, Tennessee area. Last Friday (March 6), we completed the field work on another study of personal exposure to ETS, comprising ca. 250 subjects in a sub-population of what we believe to be a demographically representative sample of the Knox County, Tennessee population. Unfortunately, very few of the personal samples have been analyzed, so we will not be able to make that data available at this time. Below, I have listed the individual materials, with comments regarding what I believe to be the most important conclusions from the studies.

Exposure to Environmental Tobacco Smoke in 16 Cities**.....**

This is the primary manuscript from the so-called 16 Cities Study. Major conclusions from the work are: a) Subjects who live and work with smokers are exposed to a lot more ETS than subjects who live and work with non-smokers, by perhaps a factor of 30 - 60. b) While it is difficult to draw direct comparisons among various exposure studies, in general, residential levels of ETS were comparable to, to somewhat smaller than, levels observed in other studies. c) Exposures to ETS (product of concentration and duration) are greater in smoking homes, vs. smoking workplaces, by a factor of 2 - 4. This is predominantly due to the amount of time spent in the former venue.

Occupational Exposure to Environmental Smoke: Results of Two Personal Exposure Studies

This is a manuscript which has been submitted to the journal Environmental Health Perspectives, and is a result of a workshop which was conducted at Johns Hopkins University and co-sponsored by OSHA, which brought together seven experts in the area of ETS exposure, to describe the state of knowledge in that area. Some of the findings described are from the 16 Cities Study, while others are from our preliminary evaluations of the restaurant/tavern servers study. Our primary conclusions from this analysis are as follows: a) Workers in facilities where smoking is permitted are exposed to 10 - 20 times more ETS than those where smoking is banned. However, in general the exposures are much lower than those which have been estimated from earlier studies. b) Restrictions clearly have the effect of diminishing exposure to ETS in the workplace. Levels encountered by subjects working in facilities where smoking was restricted to designated area were 2 - 8 times less than those experienced by subjects in facilities where smoking was not restricted. c) It is clear that some occupational sub-groups are exposed to greater levels of ETS than others. In general, it appears that the workers in the service occupations are exposed to the highest levels. However, even the most highly exposed occupational subgroup in our studies - bartenders working in single room facilities, are not exposed to levels as high as those estimated by OSHA.

Determination of Personal Exposure to Environmental Tobacco Smoke: Comparison of Salivary Cotinine Levels and Nicotine Exposure

This manuscript is being submitted to JEAEE, and focuses on the findings of the 16 Cities Study with regard to the use of salivary cotinine as a quantitative indicator of ETS nicotine exposure. General conclusions from the study are: a) Salivary cotinine levels are in good agreement with the serum levels determined in the NHANES III study. b) Misclassification rates (rates at which non-smokers or never-smokers mis-report their current smoking status) are comparable to those observed in many other studies, and for females, are substantially higher than those used by EPA in its risk assessment of the impact of ETS exposure on lung cancer. c) On an individual basis, salivary cotinine levels are not useful for predicting airborne nicotine exposure. In additional, estimation of a systemic load of nicotine based on salivary cotinine levels is probably not accurate for all but the most highly exposed individuals.

Two Presentations Regarding Personal Exposure and Area monitoring of ETS Exposures and Levels for workers in Restaurants and Taverns

These were both presented at the most recent Tobacco Chemist Research Conference. Preparation of the formal manuscript is underway. Important conclusions from this study are as follows: a) In general, bartenders are exposed to higher levels of ETS than restaurant servers, but differences are not large for subjects working in the more modern types of multi-room/area restaurants. b) Bartenders in single room taverns are exposed to higher ETS levels than those in multi-room/area facilities. c) Exposures (product of concentration and duration) of restaurant servers are not radically different from those of other workers who work in environments where smoking is not restricted. d) Area samples can be used to predict personal exposure to ETS only to within an order of magnitude.

I hope that you will find this information useful to you in making your assessments. If you have any questions about any aspect of the studies or the resulting data, I would encourage you to call me. Thank-you for this opportunity to provide input to the decision making process.

Sincerely,

Roger A. Jenkins, Ph.D.
Leader
Sampling and Analysis Group
Chemical and Analytical Sciences Division

cc: Dr. Max Eisenberg, CIAR

The following journal article was attached to Roger A. Jenkins' comments. Due to copyright infringement laws we cannot display it. We have listed the citation for your information.

National Toxicology Program
Report on Carcinogens Group

Jenkins RA, Palausky A, Counts RW, Bayne CK, Dindal AB, Guerin MR. 1996. Exposure to environmental tobacco smoke in sixteen cities in the United States as determined by personal breathing zone air sampling. Journal of Exposure Analysis and Environmental Epidemiology 6(4):473-501.

Study Objective

- Early initial examination of personal exposure of waiters, waitresses, and bartenders.
- 16 City study had limited subjects in this occupational group.

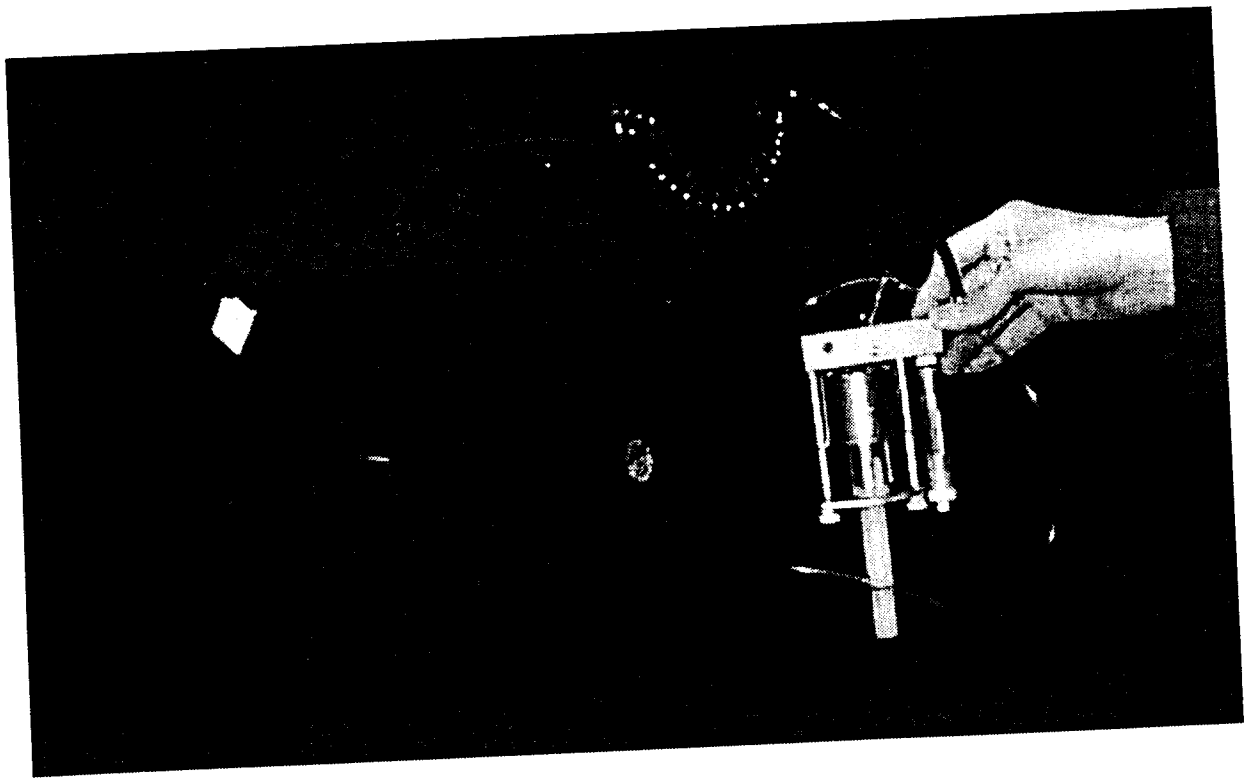
Institutional Responsibilities

- Oak Ridge National Laboratory
  - Overall study design and implementation
  - Field operations
  - Air marker analyses
  - Data management and interpreation
- The Tombras Group/Amick Research
  - Subject recruiting
  - Assistance with field operations
  - Final data coding
- Labstat-Canada
  - Salivary cotinine analyses

Experimental Design

- 80 servers and 80 non-smoking bartenders recruited.
- 4 hr minimum workshift.
- 25-seat minimum, no fast-food.
- Area samples in selected restaurants.
- Field operations: Nov. '96 - Jan. '97.
- Recruited thru managers/owners.
- Subjective information on exposure

Sampling System



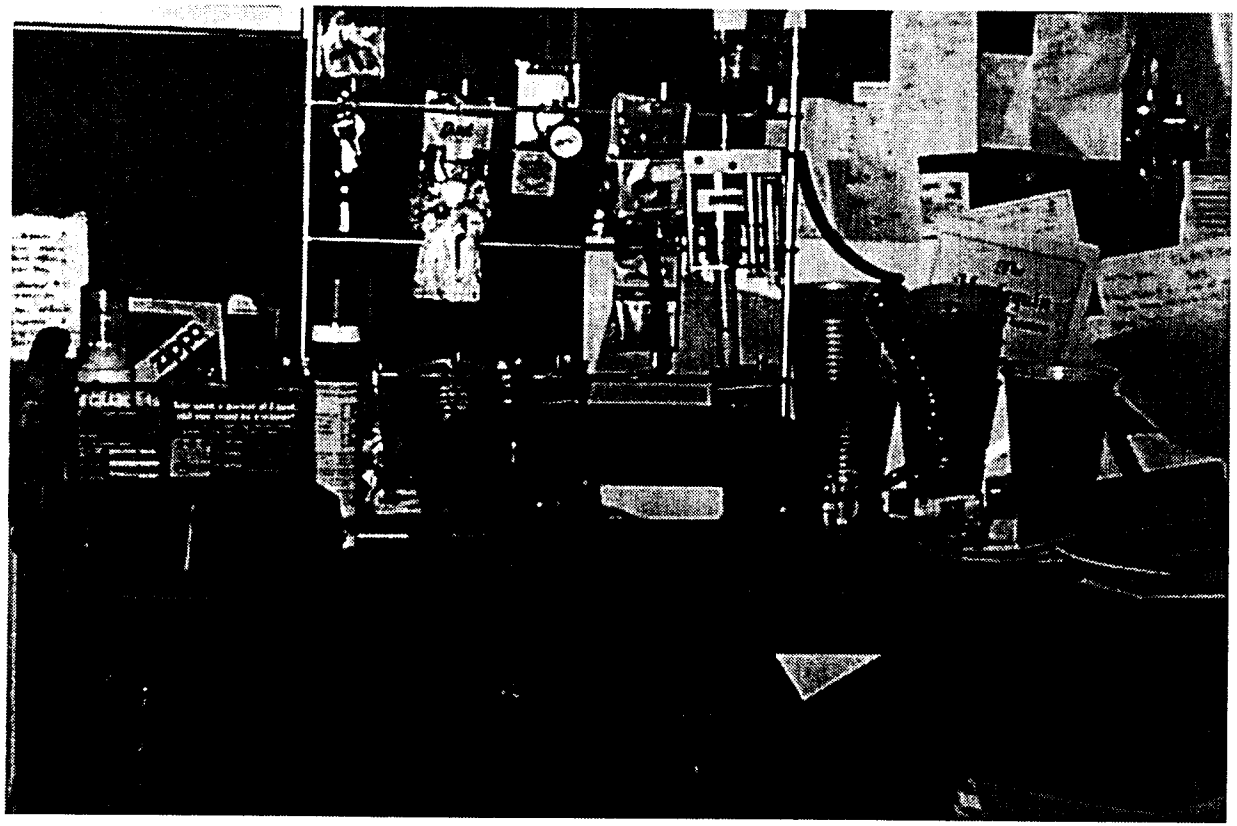
Classification of area samplers

- Bars (49)
- Smoking areas in restaurants (9)
- Non-smoking areas in restaurants (15)
- Boundary areas (8)

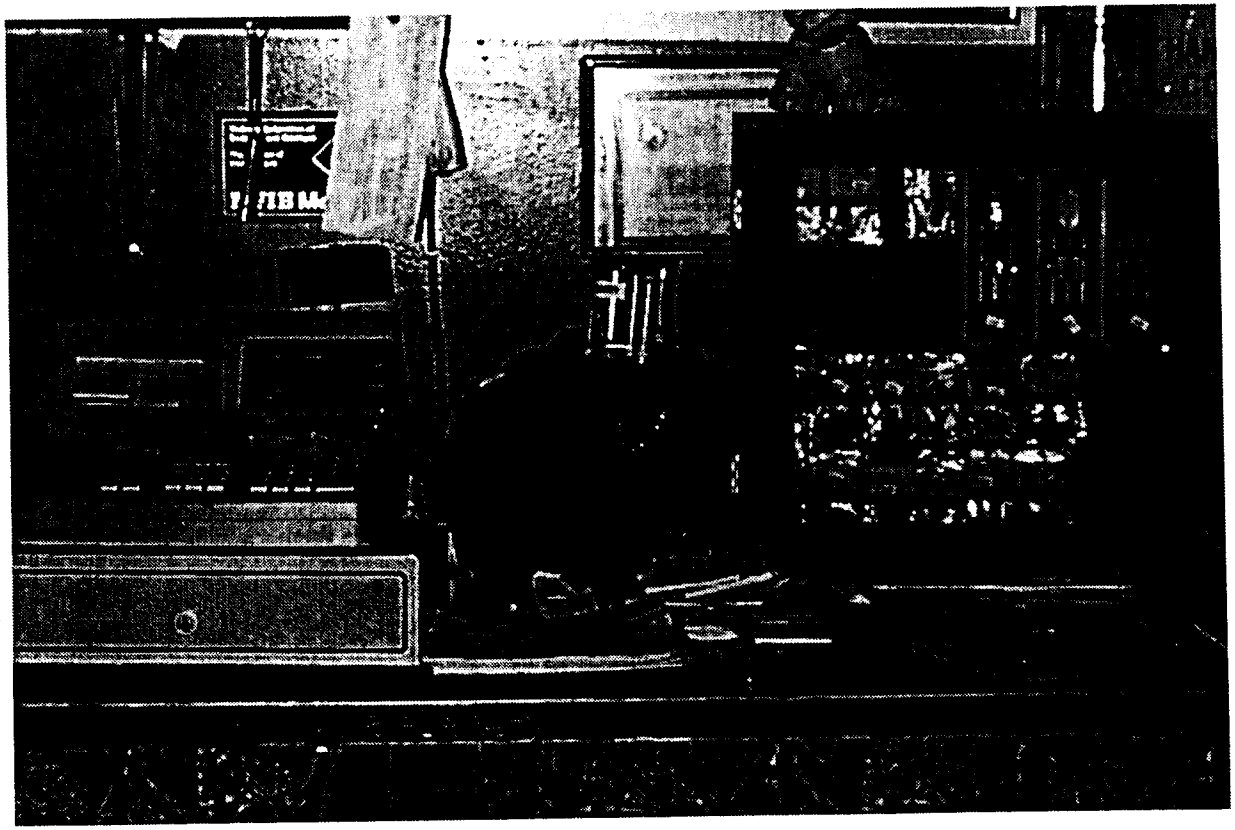
Classification by type of facility

- Single room bars
- Single room restaraunt/bar
- Restaurant only
- Multi-room restaurant/bar

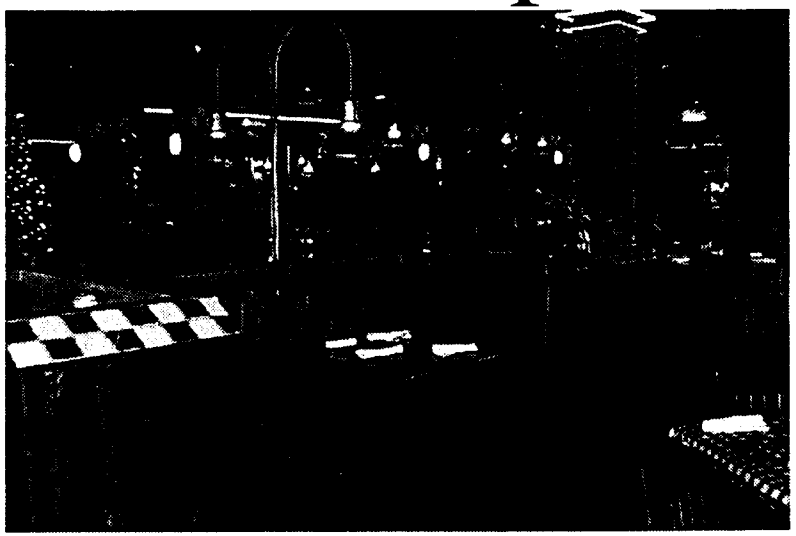
Area Samples in Bars

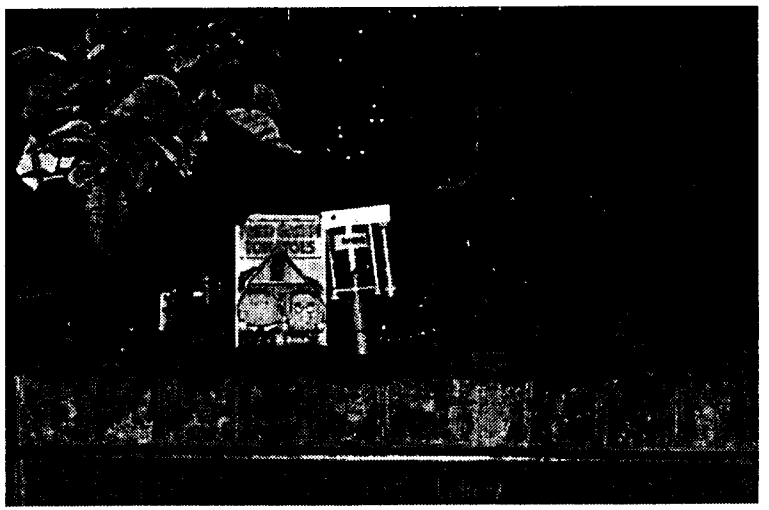


Area Samples in Bars

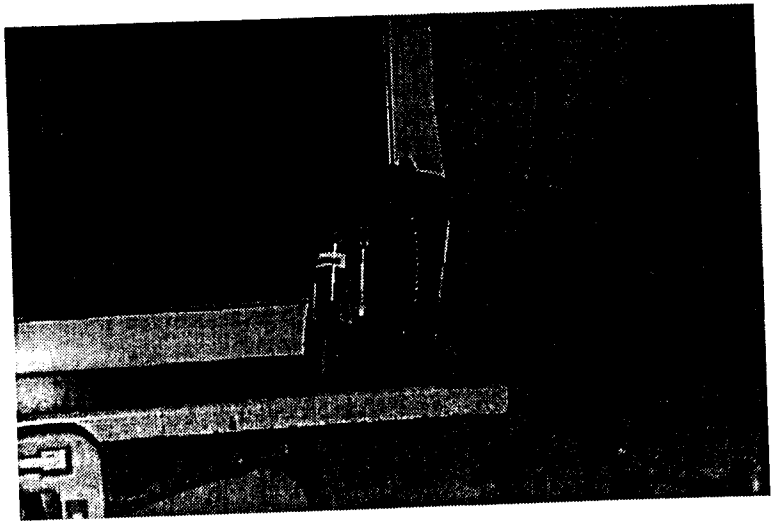


Area Samples in Restaurants





Multiroom Restaurants



Area Samples

4 - 10 hr. Samples, ug/m^3

	3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
N	85	85	85	85	85
Median	**0.78**	**2.77**	**66**	**28**	**0.81**
Mean	2.70	11.2	112	70	53
80^{th} %ile	5.42	24.7	191	121	75
95^{th} %ile	9.14	41.6	310	287	224

Levels of ETS constituents in various areas(ug/m^3)

Area type	Nicotine	Sol-PM
Bars	10.612	45.947
Smoking areas	7.789	40.565
Boundary areas	1.226	13.874
Non Smoking	0.827	14.516

Comparison of ETS Levels: Personal Sampling vs Area Samples: Single Room Bars

4 - 9 hr samples, ug/m^3

		3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
Median	**Area**	**5.3**	**19.8**	**172**	**122**	**99**
Median	Bartenders	4.9	20.6	213	140	134
80th %ile	**Area**	**8.8**	**35.8**	**296**	**169**	**165**
80th %ile	Bartenders	8.1	34.5	372	325	229

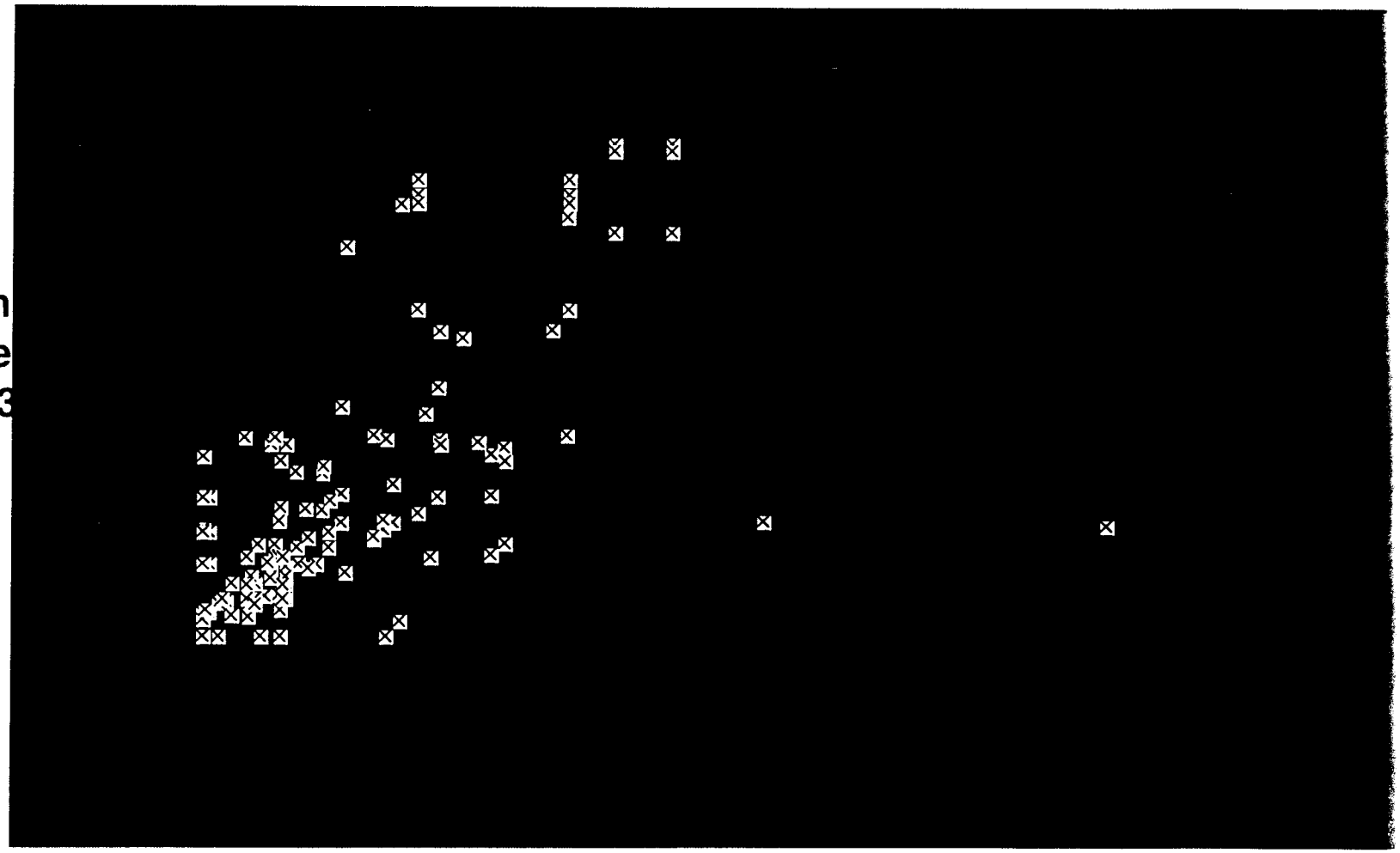
COMPARISON OF PERSONAL AND AREA SAMPLERS, GAS PHASE ANALYTES, (uG/M^3)

		3-EP		Nicotine	
Subject	Summary	Subject	Area	Subject	Area
Category	Statistic	Samples	Samples	Samples	Samples
	N	74	43	74	43
Bartender	Median	1.17	3.26	4.08	8.45
	Mean	2.90	3.97	12.82	15.60
	N	74	38	74	38
Server	Median	0.58	0.59	1.04	1.25
	Mean	1.38	1.51	4.08	7.15
Bartender	N	148	81	148	81
+	Median	0.93	0.87	3.26	2.92
Server	Mean	2.14	2.81	8.45	11.64

COMPARISON OF PERSONAL AND AREA SAMPLERS, PARTICULATE PHASE ANALYTES, (uG/M^3)

		RSP		Sol-PIM		FPM	
Subject	Summary	Subject	Area	Subject	Area	Subject	Area
Category	Statistic	Samples	Samples	Samples	Samples	Samples	Samples
	N	74	43	74	43	74	43
Bartender	Median	118.07	71.61	25.48	29.71	38.99	44.71
	Mean	160.48	143.93	82.75	85.15	100.34	99.94
	N	74	38	74	38	74	38
Server	Median	74.65	68.59	6.20	7.73	17.35	15.71
	Mean	113.98	84.35	20.33	20.72	32.52	34.21
Bartender	N	148	81	148	81	148	81
+	Median	94.28	70.88	15.55	17.21	27.98	28.16
Server	Mean	137.23	115.98	51.54	54.93	66.43	69.11

Personal vs. Area Samples, RSP



Correlation Between Personal and Area Samples

ETS Marker	Correlation
RSP	0.78
Solanesol	0.90
UVPM	0.89
FPM	0.91
3-EP	0.80
Nicotine	0.79

Comparison With Previous Work

	ORNL				*Seigel*	
	Single Room Bar	Single Room Bar/Rest-aurant	Rest-aurant only	Multi-room Bar/ Rest-aurant	Bars	Rest-aurants
Nicotine (ug/m3)	22.3	10.4	1.76	5.27	19.7	6.5
RSP (ug/m3)	180	78	69	78	348	117

Source: Seigel, JAMA, July 28, 1993, vol. 270, No. 4

Observations and Conclusions

- Area samples in bars had the highest concentration of ETS markers, followed by smoking areas, boundary areas, and non-smoking areas.
- Wide range of ETS levels encountered.
- Area samples provide relatively good estimate of personal exposure.
- Particulate phase markers give higher correlations between area samples and personal samplers than do gas-phase analytes.
- Reasonable comparability with previous work.

Initial Determination of Occupational Exposure to Environmental Tobacco Smoke Among Non-Smoking Restaurant Servers and Bartenders in One US City

Roger A. Jenkins, Amy B. Dindal,
Michael P. Maskarinec, and Richard W. Counts
Oak Ridge National Laboratory
Oak Ridge, TN 37831-6120

*Presented at the 51st Tobacco Chemists Research Conference,
Winston-Salem, NC September 14 - 17, 1997

Acknowledgement

Research sponsored by the ***Center for Indoor Air Research*** under contract No. ERD-88-812 with the Oak Ridge National Laboratory, managed by
Lockheed Martin Energy Research Corp. for the
US. Department of Energy,
under contract DE-AC-05-84OR9622464.

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Study Objective

- Early initial examination of personal exposure of waiters, waitresses, and bartenders.
- 16 City study had limited subjects in this occupational group.

Experimental Design

- 80 servers and 80 non-smoking bartenders recruited.
- 4 hr minimum workshift.
- 25-seat minimum.
- Area samples in selected restaurants.
- Field operations: Nov. '96 - Jan. '97.
- Recruited thru managers/owners.

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Institutional Responsibilities

- Oak Ridge National Laboratory
  - Overall study design and implementation
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  - Data management and interpreation
- The Tombras Group/Amick Research
  - Subject recruiting
  - Assistance with field operations
  - Final data coding
- Labstat-Canada
  - Salivary cotinine analyses

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Fanny pack eases wearing of sampling pump

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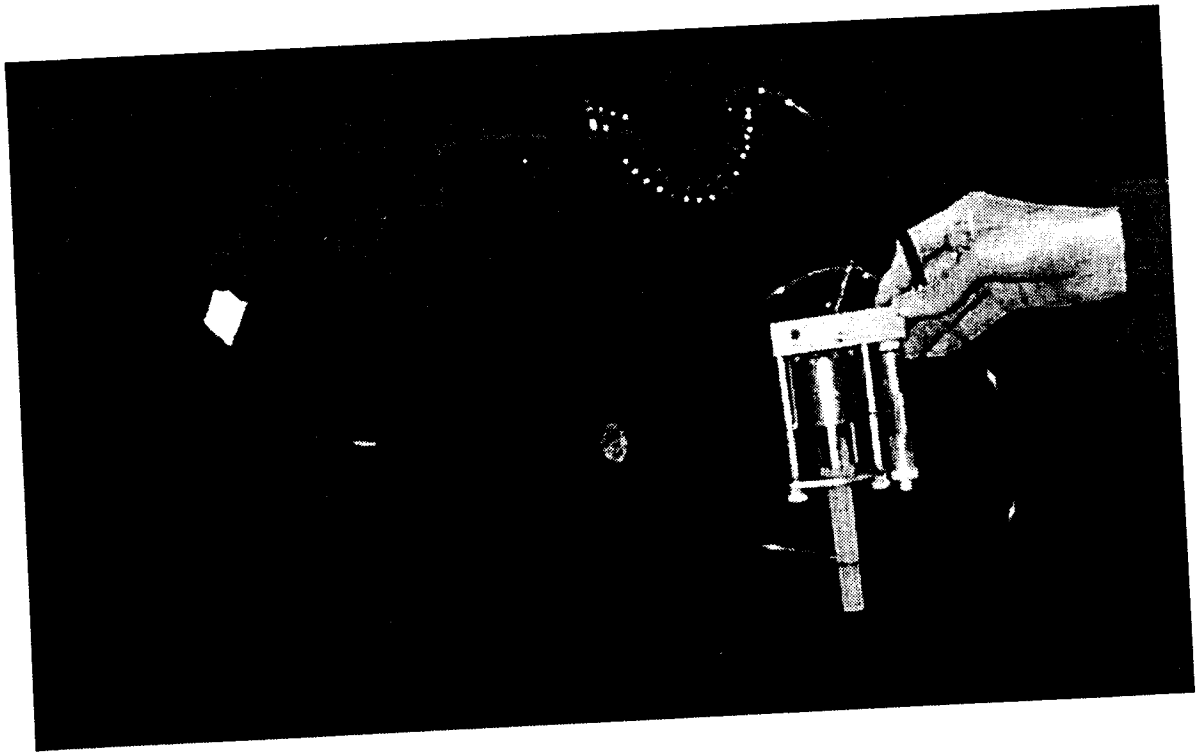
Sampling System



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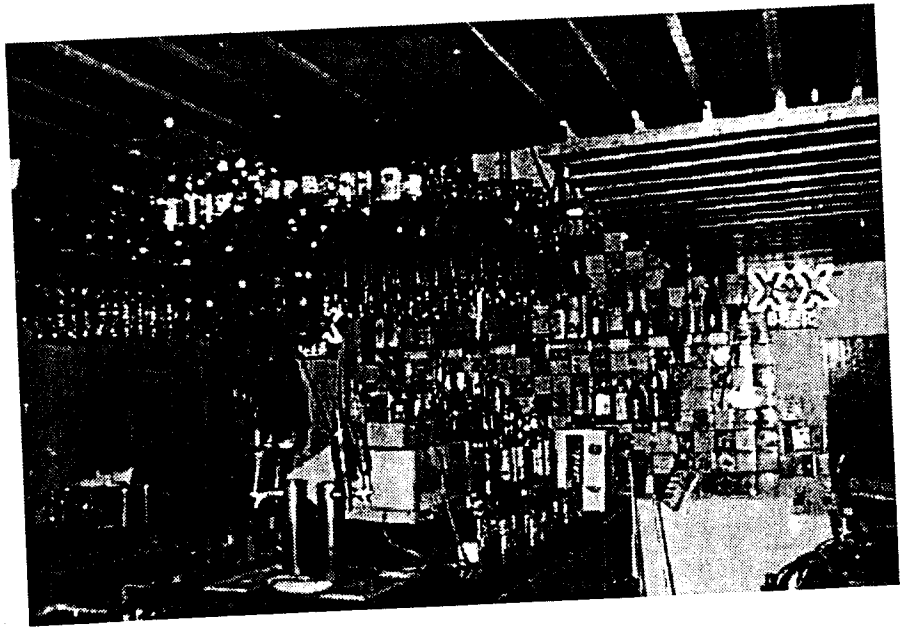
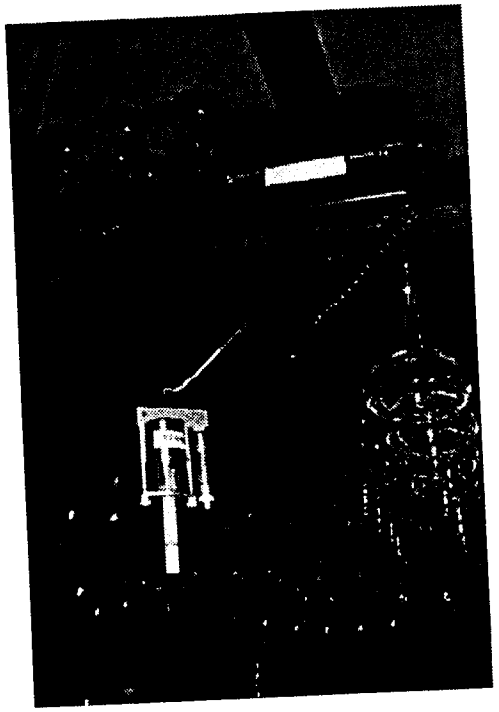
Area Samplers Placed in Most Facilities

Overview



Detail



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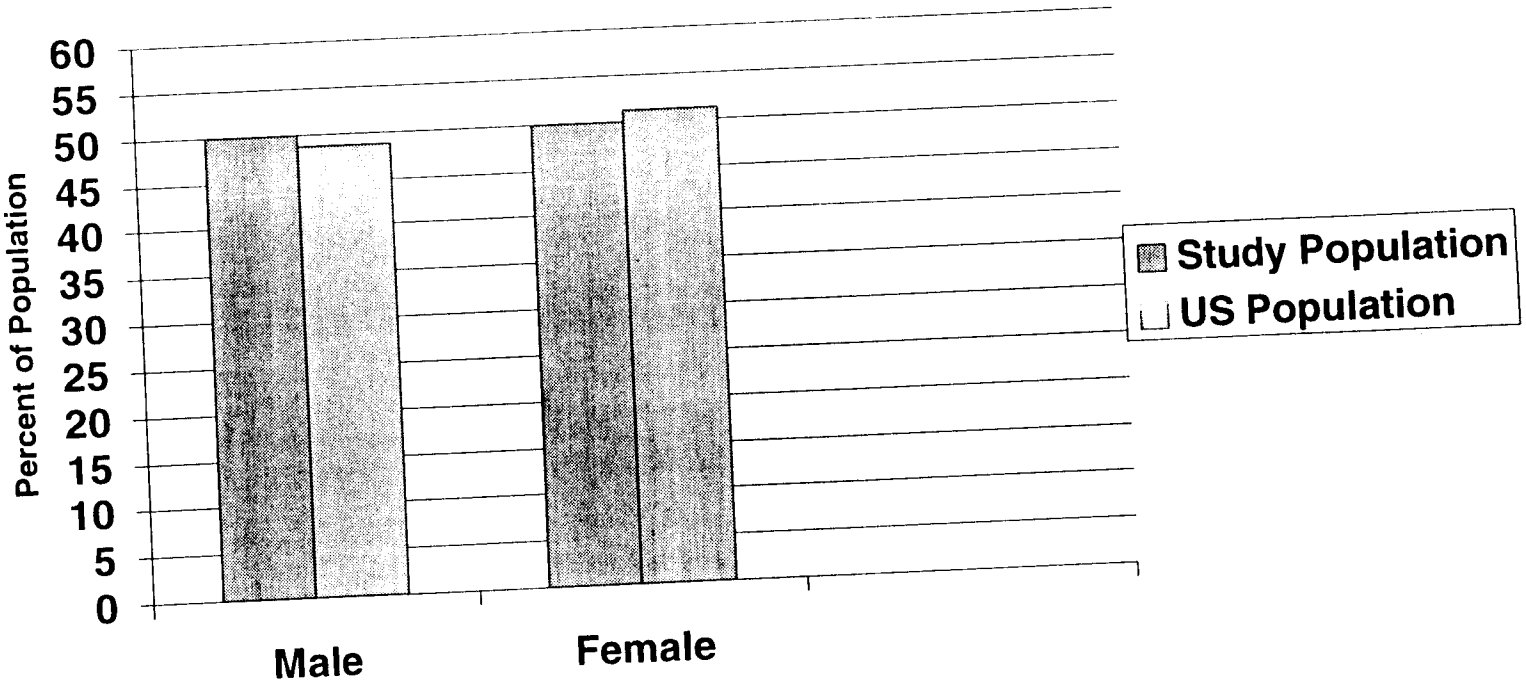
Subject Demographic Comparisons: Gender



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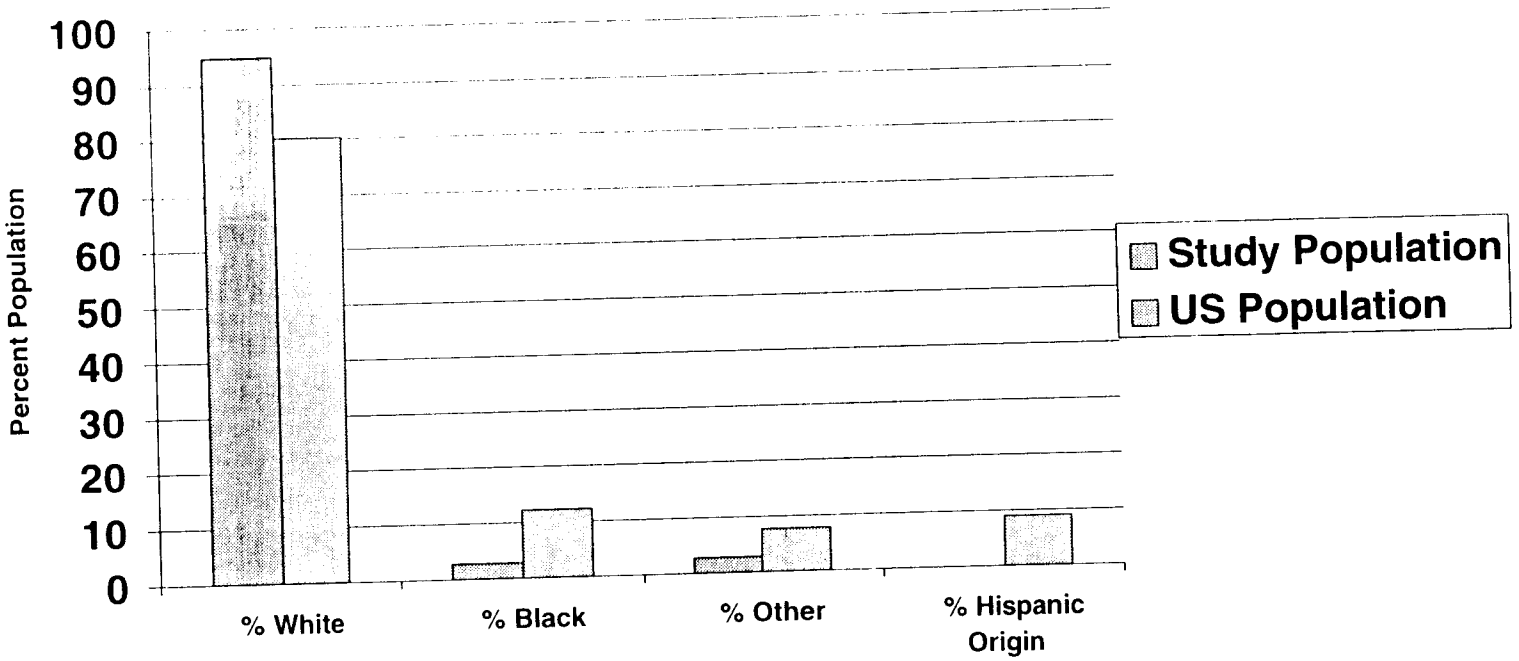
Subject Demographic Comparisons: Race



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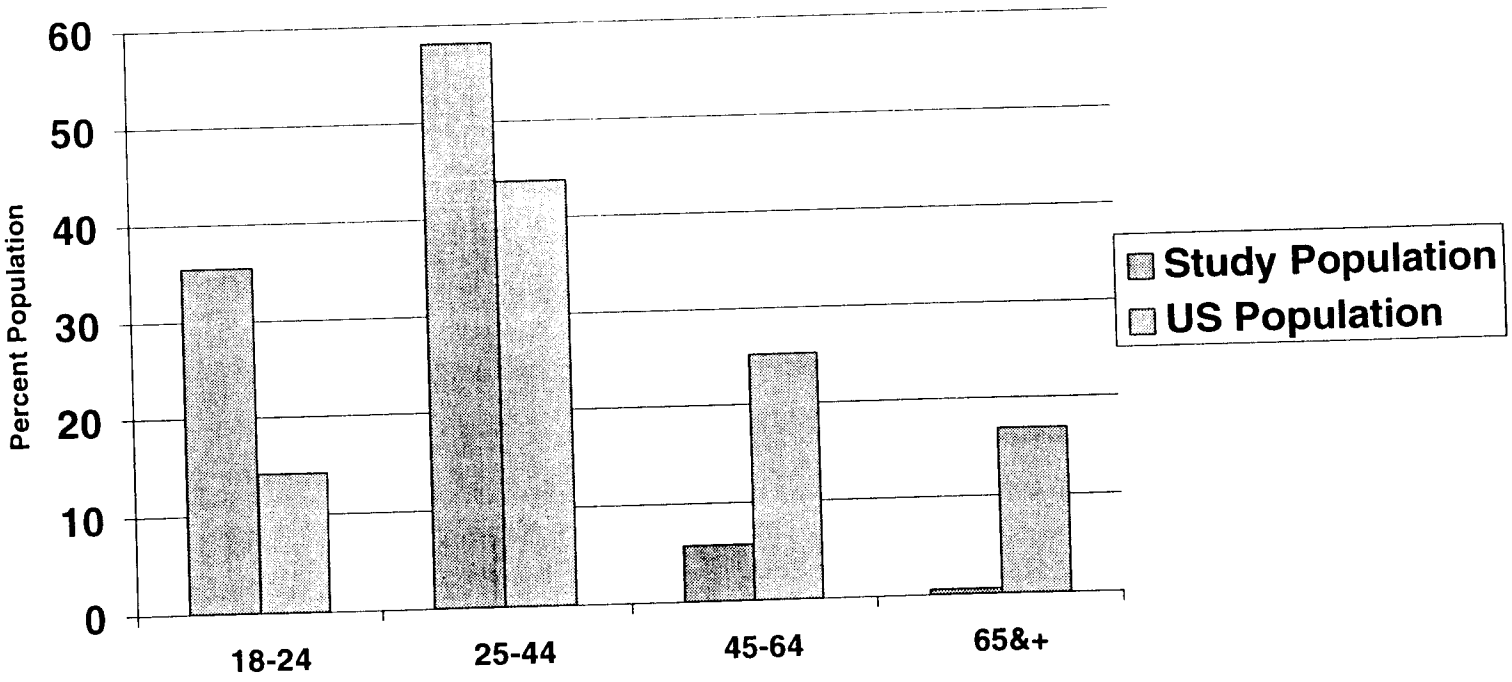
Subject Demographic Comparisons: Age



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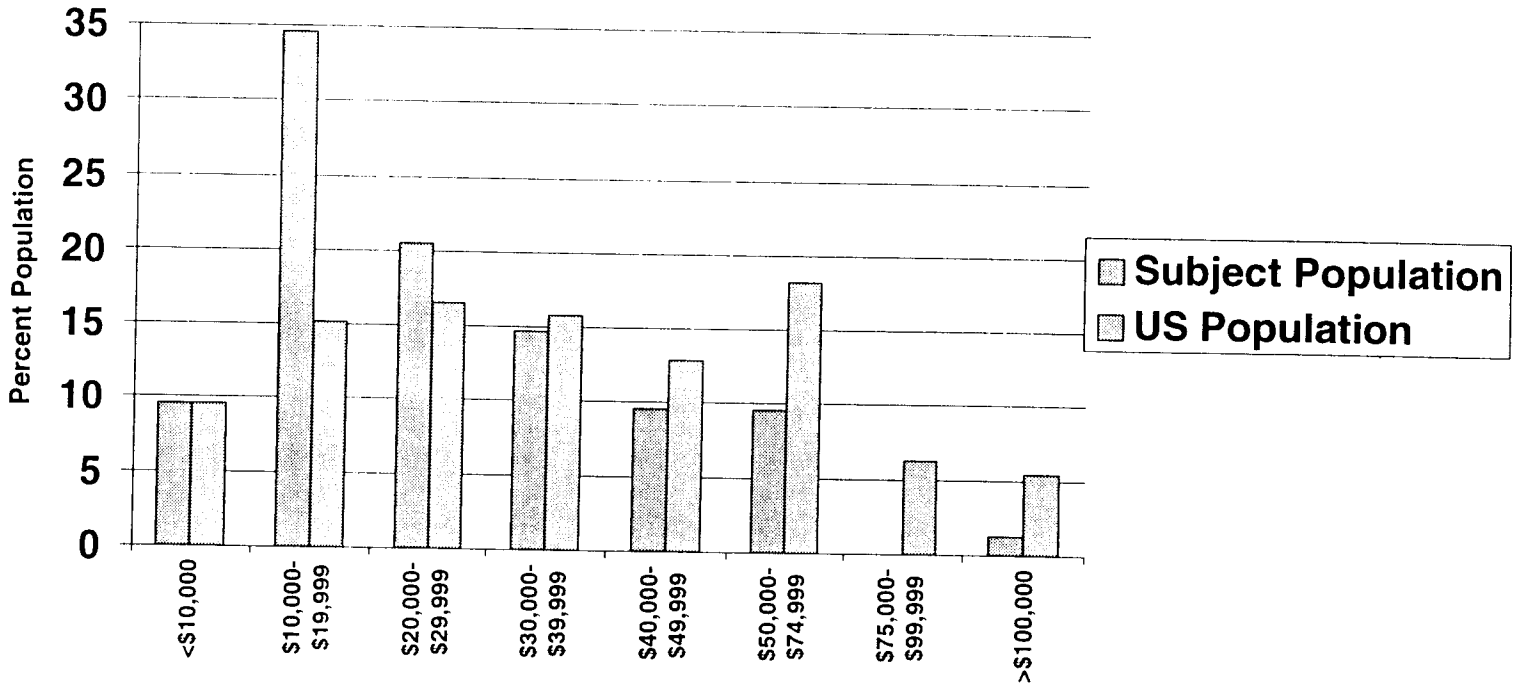
Subject Demographic Comparisons: Household Income



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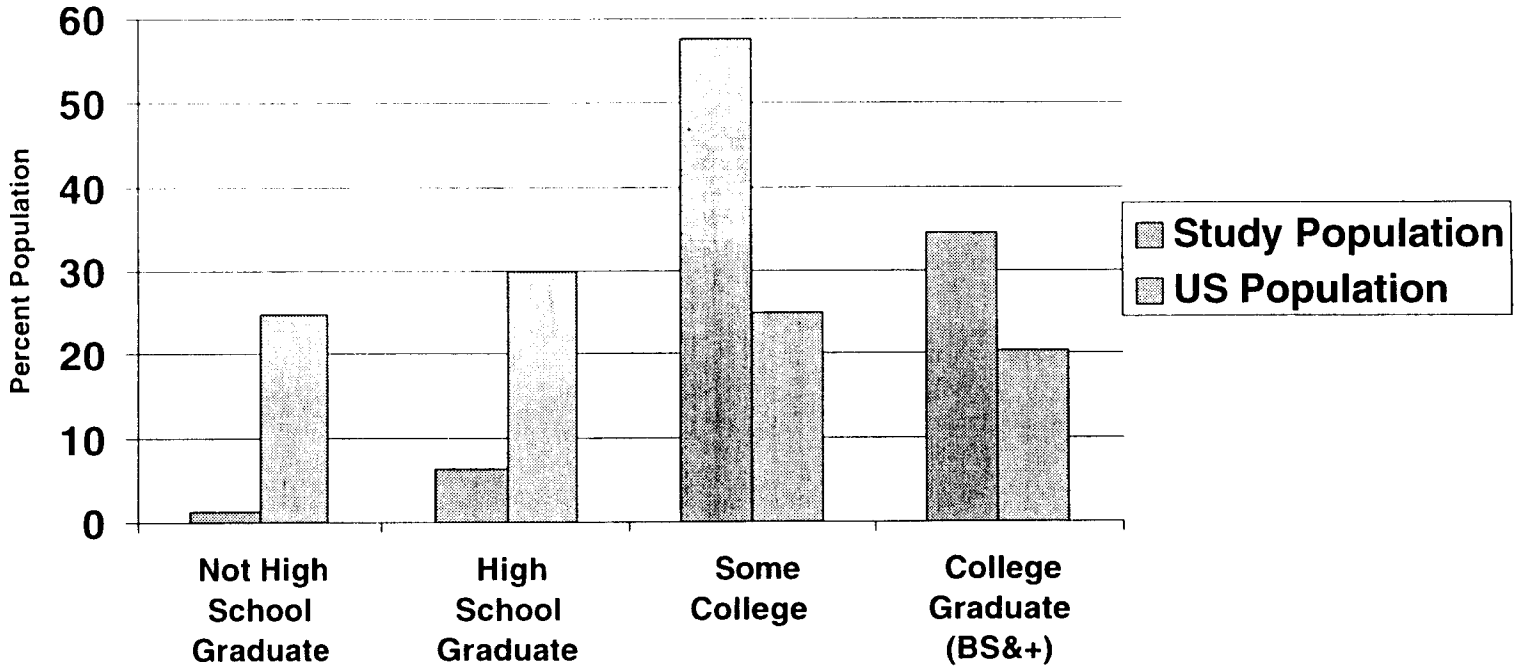
Subject Demographic Comparisons: Educational Attainment



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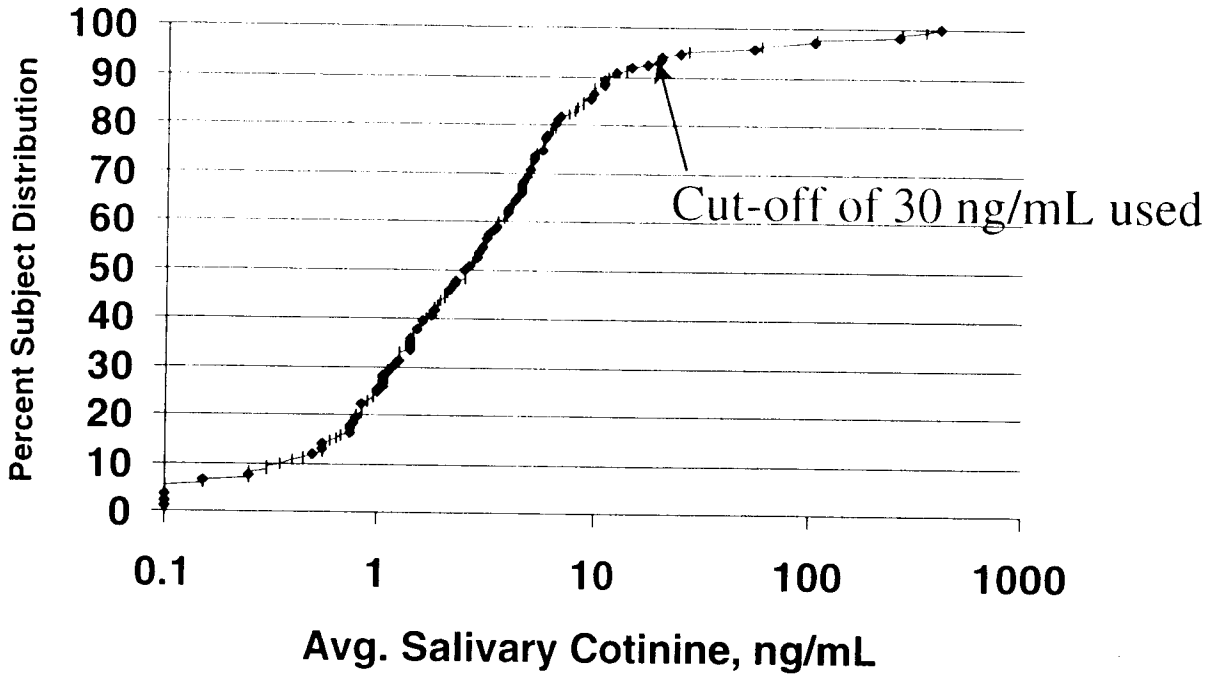
Distribution of Average Salivary Cotinine Levels



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Levels to Which **All Servers*** Were Exposed

4 - 9 hr samples, ug/m^3

	3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
N	82	82	82	82	82
Median	**0.60**	**1.22**	**81**	**20**	**7.6**
Mean	1.75	5.88	109	37.4	26
80th %ile	2.59	6.06	174	56	37
95% ile	6.68	28.6	382	127	123

*Corrected for high salivary cotinine.

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Levels to Which Bartenders* Were Exposed

4 - 9 hr samples, ug/m^3

	3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
N	80	80	80	80	80
Median	**1.17**	**4.45**	**112**	**41**	**27**
Mean	3.30	14.1	151	98	77
80th %ile	5.83	26.3	235	157	138
95th %ile	10.0	43.3	420	363	350

*Corrected for high salivary cotinine.

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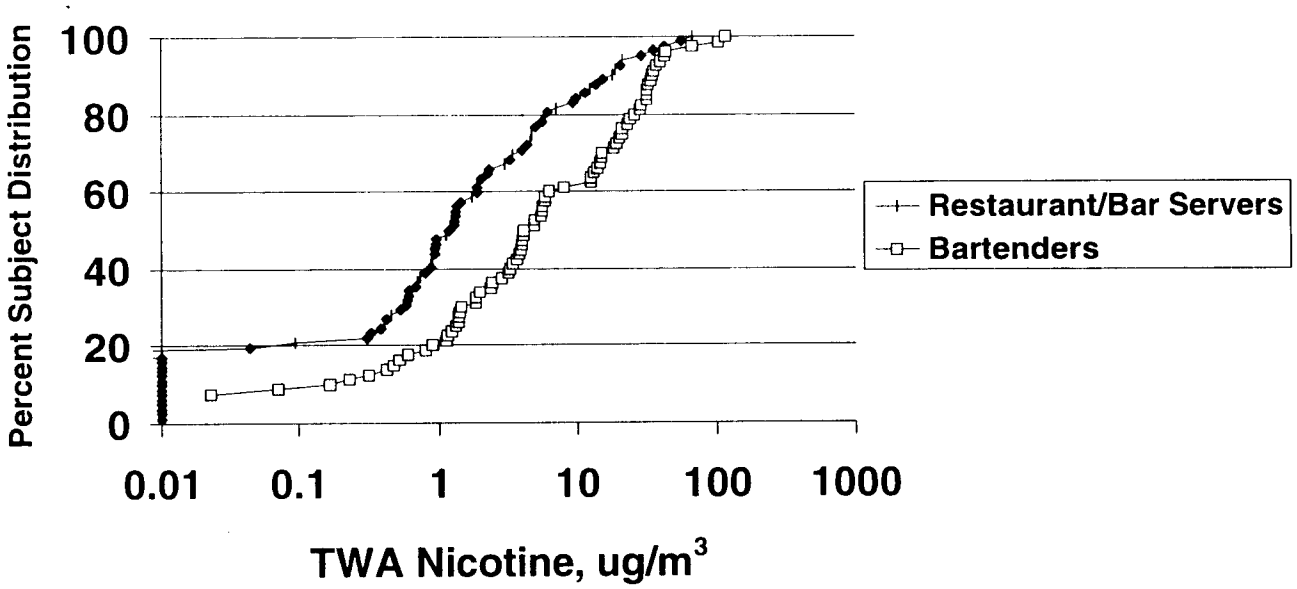
Subject Distributions:
Servers vs. Bartenders



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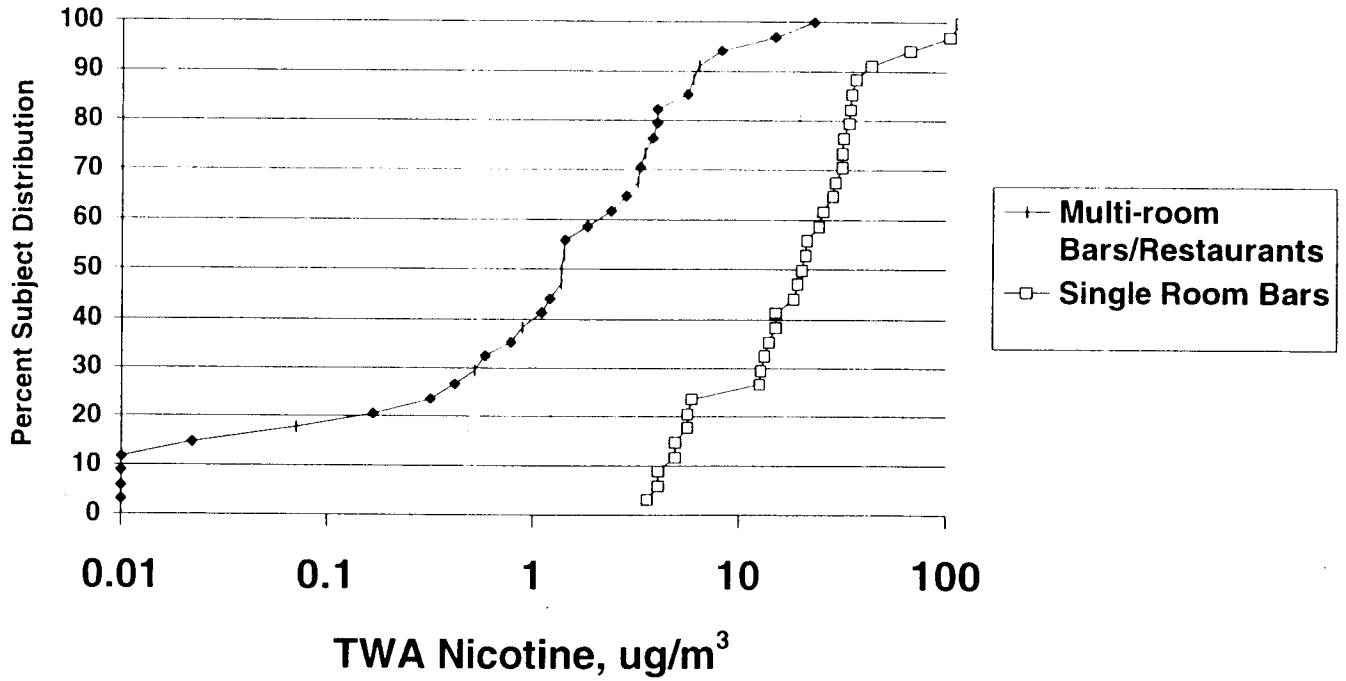
Distributions of Bartenders:
Multi-Room Bar/Restaurants vs. Single Room Bars



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Personal Exposure Comparisons in Multiroom Restaurant Bar Combinations: Servers vs. Bartenders

4 - 9 hr samples, ug/m^3

		3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
Median	**Servers**	**0.59**	**0.87**	**78**	**19**	**7**
Median	Bartenders	0.73	1.39	68	28	14
80^{th} %ile	**Servers**	**1.40**	**4.14**	**136**	**39**	**26**
80^{th} %ile	Bartenders	1.49	3.92	142	48	39

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Comparison of Workplace ETS Personal Exposure Levels: This Study (*N = 162*) vs "16 Cities" (*N = 14*) Servers and Bartenders Combined

4 - 9 hr samples, ug/m^3

		3-EP	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
Median	**This Study**	**0.91**	**2.32**	**98**	**30**	**18**
Median	"16 Cities"	1.12	3.83	42.8	15	5
Mean	**This Study**	**2.52**	**9.95**	**130**	**68**	**51**
Mean	"16 Cities"	2.09	6.66	61.9	37	25

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Comparison of Median *Exposures*: Restaurant Servers vs. 16 Cities Subjects in Workplaces where Smoking was Unrestricted

Exposure = concentration x time, ug-hr/m^3

	Shift Length, Hrs	*3-EP*	*Nicotine*	*RSP*	*FPM*	*Sol-PM*
Servers	**4.6**	**2.9**	**5.6**	**382**	**91**	**38**
Bartenders	5.2	5.8	22.4	575	209	129
16 Cities Subjects	8.24	3.9	8.5	306	59	9

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Observations and Conclusions

- Young, well educated subject base.
- Wide range of ETS levels encountered (eg. 0.5 - 116 ug/m^3 nicotine).
- Mis-classification rate for non-smokers comparable to other studies. (>30 ng/mL: 8/170, or 4.7%)
- Bartenders exposed to higher ETS levels than servers.
  - However, differences are not large for subjects in larger, multi-room restaurants with bars.
- Bartenders in single room taverns are exposed to higher ETS levels than those in multi-room restaurant-bars.
- Exposures of restaurant servers are not radically different from those of other workers in environments where smoking is not restricted, but those of bartenders are higher.

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